[**Each hospital to use its own Patient Information Sheet and Informed Consent according to local requirements on local headed paper**]

The REVERSE-QoL study (pREVention and management tools for rEducing antibiotic Resistance in high prevalence Settings – Quality of Life)

Information for ALL Patients

We are inviting you to take part in a research study called REVERSE-QoL, which is being carried out in a number of hospitals in Greece, Italy, Romania and Spain. The study is funded by the European Union.

Before you decide if you want to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information sheet carefully or ask someone to read it to you. Please discuss it with others if you wish. We will give you a copy to keep. Please ask the nurses or doctors if there is anything that is not clear or if you would like more information. **Joining the REVERSE-QoL study is entirely voluntary.** Please take time to decide whether or not you wish to take part.

You may decide that you do not wish to take part now or you may wish to take part now but then decide later to withdraw from the study. Your decisions will not influence the care you receive now or in future. We hope that if you decide to join the study but withdraw later, you would give a reason for your decision, but you do not have to do this if you do not want to.

What is our reason for doing the REVERSE-QoL study?

Antibiotic resistant bacteria can cause serious infections. To be able to justify potentially expensive measures that prevent infections with these bacteria, we need to better understand the long-term impact these infections on the Quality of Life of patients.

We want to what extent and for how long patients have a lower Quality of Life due to getting an infection caused by antibiotic-resistant bacteria during the hospital admission.

This study will help to distinguish whether and how antibiotic-resistant infections are affecting patients up to 1 year after the date they got infected. It will help us to identify the impact of those infections from a patient's perspective, which is also needed to work out the value for money of strategies that reduce the change of getting infected.

Why have I been invited to take part?

You have been invited to take part in this study because you have been admitted to a hospital that takes part in a large study evaluating the impact of different types of strategies that may reduce the chances of getting infected during your hospital stay. All patients that get infected with an infection caused by specific antibiotic-resistant bacteria (Carbapenem-resistant *Acinetobacter baumannii*, Carbapenem-resistant Enterobacteriales, or Carbapenem-Resistant *Pseudomonas aeruginosa*) during their hospital stay in one of the participating hospitals are invited to take part in this study focusing on the impact of these infections on quality of life. Also a random selection of patients that are not infected by these bacteria are invited to take part into this study (2 uninfected persons for each infected person). Hence, you are invited to take part in this study so that we can compare your perspectives to that similar patients with(out) bloodstream infection.

Do I have to take part?

No. It is up to you to decide whether or not to take part. Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason, by advising us of this decision. Any personal data will be destroyed. The deadline by which you can withdraw any information you have contributed to the research is anytime priot to completing the 12 month follow up. If you decide to withdraw your data, any data that has already been collected will be removed from the database.

What will happen to me if I take part?

If you decide to take part in this study a nurse will ask you to sign a consent form and to complete a short paper questionnaire. The paper form will ask about your current quality of life and your contact details so we can ask you to complete the questionnaire again 1, 3, 6 and 12 months after you have completed the form the first time. The questionnaire can be completed at your own pace, but takes usually 8-15 minutes to complete.

Are there any risks in taking part?

The risks are small. You may experience some anxiety as you remember your illness and reflect on how it has impacted your life.

What are the possible benefits of taking part?

You may experience an overall positive feeling in that your illness is being researched and your quality of life is being given consideration. Entering this study may not directly help you, but the information we get from the REVERSE-QoL study should help patients like you in the future.

What information will be collected and why is the collection of this information relevant for achieving the research objectives?

We will collect data on your quality of life using two validated questionnaires: the EuroQol 5D (EQ-5D) and the 36-Item Short Form Survey (SF-36). In addition, we will collect information on your age, sex, time in the hospital, any surgery performed or antibiotic used in the past 30 days, and any underlying chronic diseases you may have. The latter is needed to adjust for any relevant potential differences between infected and uninfected patients that may explain (absence of) observed differences between infected and uninfected patients.
Identifiable data (including consent forms) will be stored in a secure online system behind the University of Zurich's firewall. Only researchers that need to have access to the data will be able to see it. The data will be stored for 5 years. Other research data will be stored for 10 years after publication or public release of the work of the research.

What about protecting my confidentiality?
Information about you will be kept confidential and will not be made available to anyone who is not connected with the REVERSE-QoL study. Your medical notes and study information will be available to study staff. Strict confidentiality will be maintained at all times. Your name will never be used for study information; these will be identified only by a study number (hospital site number (4 digits) and sequentially assigned subject number).

Will the research be published? Could I be identified from any publications or other research outputs?

The findings from the research will be written up in an academic publication. You won't be able to identify yourself from the outputs as only aggregated (not at an individual level) will be reported.

Leaving the study
You may withdraw from the study at any time, but if you do it would help us if you are able to tell us the reason for this. However you do not need to tell us if you do not want to.

How can I join the REVERSE-QoL study?
After you have read this information sheet, we will ask you to give consent to be seen by the nurse.

If you would like more information or have any questions about the REVERSE-QoL study please ask the doctors, nurses or counsellors. If you still need more information, please call:

Insert names and telephone numbers as appropriate:
Name:

Telephone Number: …….

If you decide to join the REVERSE-QoL study and have any concerns about any aspect of the REVERSE-QoL study in the future, please also contact ..... on the telephone number above. If you remain unhappy and wish to complain formally, you can do this following the standard Hospital Complaints Procedure (details can be obtained from ..... on telephone number ..... as above).

(To be presented on local-headed paper")
Version 1.1 Date 11 October 2015

REVERSE-QOL: pREVention and management tools for rEducing antibiotic Resistance in high prevalence SEttings – Quality of Life

Please initial (or mark) box if you agree:

I confirm that I have read/ been read the patient information sheet (version 1.1 dated 11 October 2021) for the REVERSE-QoL study and that I understand what will be required of me if I participate in the study. The study has been explained to me and I have had an opportunity to ask any questions I have about the study.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I understand that sections of any of my medical notes may be looked at by responsible individuals involved in the running of the study where it is relevant to my taking part in research. I give permission for these individuals to have access to my records, but understand that strict confidentiality will be maintained.	
I understand that I will be asked to complete a questionnaire 5 times in total over a period of 1 year.	
I agree to take part in the REVERSE-QoL study.	

	Name	Email	Telephone number
Participant			

Participant's signature	Print name	Date (day/month/year)

Signature of person delegated to take consent	Print name	Date (day/month/year)

IMPORTANT: one signed original to be kept in REVERSE-QoL study file by the researcher
one signed copy to be given to the patient
one signed copy to be kept in the clinic file